Illegal clinical trial by GVK Bio-Science

948. SHRI UDAY PRATAP SINGH: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that M/s GVK Bio-Science was doing illegal clinical trials for M/s Glenmark and Ranbaxy and US Muiti National Company, Pfizer as recently reported in media; and

(b) if so, the details of the case and what action has been taken by DCGI in this matter?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) The news reports in May, 2004, alleging conduct of illegal clinical trial by M/s GVK Bio-Science Hyderabad, were investigated by State Drug Control Authorities, Andhra Pradesh and sub-zonal office of Central Drugs Standard Control Organization (CDSCO) at Hyderabad.

As per investigation report, M/s GVK Bio-Sciences Hyderabad, had not undertaken clincial trials, for which prior permission is required. The firm had conducted bio-equivalence study in March-April, 2004, for M/s. Glenmark Pharma for their formulation Oxybutine Hydrocloride, M/s. Ranbaxy Laboratories Ltd., Gurgaon for their formulations Azithromycin and Clarithromycin. The studies had been undertaken after due approval obtained from institutional Ethics Committee. The drugs in question are approved and well established in the country.

Current population of India

949. SHRI MANOJ BHATTACHARYA: Will the Minister of HEALTH AND FAMILY-WELFARE be pleased to state;

(a) the present population of the country as on April, 2004 together with the present birth rate;

(b) whether the various schemes launched so far to stabilize the country's population have yielded any positive results and if so, the details thereof; and

(c) If not, steps propsoed to be taken in this direction to encourage small family norms in the country?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) The population as on April, 2004 is 108.13 crores and the estimated birth rate of 2004 is 25.0 per thousand population.

(b) and (c) Yes, Sir. The Birth Rate, Infant Mortality Rate and Total Fertility Rate are the basic indicators of success of population stablization measures. These indicators are on declining trends as given below:

Year	C.B.R.	I.M.R.	T.F.R.
1990	30.2	80	3.8
1995	28.3	74	3.5
2000	25.8	68	3.2
2002	25.0	63	Not available

Further the Government is addressing the issue of population stabilization by focusing on improved access to comprehensive integrated health services, including sustained behavioural change communication and improved access to Family Planning services in high fertility States.

Ban on gutkha and pan masala

950. SHRI RAVULACHANDRA SEKAR REDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether many States including the State of Andhra Pradesh have requested the Union Government for issuance of notification for banning manufacture and sale of gutkha and pan masala in their States;

(b) if so, the action taken by Government on their request; and

(c) by which date the notification is likely to be issued enabling the States to ban the manufacture/sale of gutkha and pan masala in their States?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) Yes Sir, the Central Government has received the requests from Government of Maharashtra and Andhra Pradesh to ban manufacture and sale of gutkha and pan masala in their States.